UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

DANIEL WELZ,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Case No. 4:24 CV 820 CDP
	)	
BOSTON SCIENTIFIC CORP.,	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER

Plaintiff Daniel Welz was implanted with a Boston Scientific A219 MRI compatible subcutaneous cardioverter defibrillator pulse generator (hereafter, ICD) at a Missouri hospital in October 2020. He immediately began experiencing complications related to his device, including the failure to provide a shock when necessary, failure to transmit, and frequent errors lights. As a result of the complications, the ICD was removed and replaced with a different device. The ICD was later recalled. Welz alleges that the ICD's failure to work properly was caused by manufacturing defects and brings Missouri state law claims for strict liability, negligence, and failure to warn.[1]

[1] The Amended Complaint brings the following four claims under Missouri common law: Strict Liability—Defective Product (Count I); Strict Liability—Failure to Warn (Count II); Negligence—Defective Product (Count III); and Negligence—Failure to Warn (Count IV).

Before me now is Boston Scientific's Rule 12(b)(6) motion to dismiss. Boston Scientific argues that Welz's claims are preempted by the 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act. Because I find that Welz's claims rooted in manufacturing defects are not preempted, I will deny Boston Scientific's motion as to those claims. However, the motion is granted to the extent the Amended Complaint alleges design defects and failures to warn.

Motion to Dismiss Standard

The purpose of a motion to dismiss under Rule 12(b)(6) is to test the legal sufficiency of the complaint. When considering a 12(b)(6) motion, the court assumes the factual allegations of a complaint are true and construes them in favor of the plaintiff. *Neitzke v. Williams*, 490 U.S. 319, 326–27 (1989). Rule 8(a)(2), Fed. R. Civ. P., provides that a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." In *Bell Atlantic Corp. v. Twombly*, the Supreme Court clarified that Rule 8(a)(2) requires complaints to contain "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action." 550 U.S. 544, 555 (2007); accord *Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009). Specifically, to survive a motion to dismiss, a complaint must contain enough factual allegations, accepted as true, to state a claim for relief "that is plausible on its face." *Twombly*, 550 U.S. at 570. The issue in considering such a motion is not whether the plaintiff will ultimately

prevail, but whether the plaintiff is entitled to present evidence in support of the claim. *See Neitzke*, 490 U.S. at 327.

The Medical Device Amendments

In 1976, Congress passed the Medical Device Amendments (MDA) to the Food, Drug and Cosmetic Act (FDCA). *See* 21 U.S.C. § 360c et seq. The amendments authorized the FDA to "regulate the safety and effectiveness of medical devices." *In re Medtronic, Inc.*, 623 F.3d 1200, 1203 (8th Cir. 2010). Through the amendments, which were a response to proliferation (and frequent failure) of medical devices entering the market, Congress "swept back some state obligations and imposed a regime of detailed federal oversight." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008); *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996) (MDA was enacted in "response to the mounting consumer and regulatory concern").

The MDA classifies medical devices into three groups (Classes I, II, and III) based on the degree of risk they pose. In general, Class III devices—as the most dangerous—are subject to the highest level of scrutiny by the FDA. This manifests in a rigorous, comprehensive inquiry called "premarket approval," or PMA. *See Lohr*, 518 U.S. at 477 (noting that it takes the FDA an average of 1,200 hours to review an application for PMA). An applicant seeking PMA for a Class III device must supply information to the FDA, including a description of the device, clinical

safety trials, methods of product testing, design of the device and manufacturing controls, outcome evaluation, and proposed labeling. *Sullivan v. Medtronic, Inc.*, 498 F. Supp. 3d 1106, 1110 (E.D. Mo. 2020). The FDA does not conduct independent testing on a medical device in a PMA application. *Id.* Following PMA, an applicant must comply with certain FDA requirements and federal regulations, including those set out in 21 C.F.R. Pt. 803, 21 C.F.R. Pt. 820, and 21 U.S.C. §§ 351–52. *Id.* The holder must also comply with specifications imposed during the PMA process for the device. *Id.*

ICD's PMA and Recall

Although not pleaded in the Amended Complaint, it is a matter of public record (and not disputed by Welz) that the ICD is a Class III device approved by the FDA through the supplemental PMA process. *See* 78 Fed. Reg. 17415–16 (Mar. 21, 2013) (listing the original September 28, 2012 PMA approval for the Subcutaneous Implantable Defibrillator (S-ICD) System, PMA No. P110042).[2] This Court may take judicial notice of the PMA and PMA Supplement approvals because they can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned. *See* Fed. R. Evid. 201(b)(2); *see also*

[2] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P110042 (last reviewed August 12, 2024) (providing links to the original PMA approval letter and all applicable supplements, including Supplement No. S058, which lists the August 8, 2016 supplemental PMA approval for the Boston Scientific Model A219 EMBLEM MRI S-ICD).

Antonacci v. Allergan USA, Inc., Case No. 4:20CV1841 AGF, 2021 WL 3404024, at *1 n.2 (E.D. Mo. Aug. 4, 2021) (taking judicial notice of a breast implant PMA and noting that "[t]he Court may take judicial notice of public records and consider them on a motion to dismiss") (citing *Stahlv. U.S. Dep't of Agric.*, 327 F.3d 697, 700 (8th Cir. 2003)); *Arthur v. Medtronic, Inc.*, Case No. 4:14CV52 CEJ, 2014 WL 3894365, at *1 n.1 (E.D. Mo. Aug. 11, 2014) (taking judicial notice of PMA approval). A PMA and PMA Supplement are both subject to the same rigorous standards of review. *Riegel*, 552 U.S. at 319 (citing 21 C.F.R. § 814.39(c)). The original and supplemental PMAs remain in effect for the ICD, and have never been suspended or revoked.

The Amended Complaint alleges that on or about December 2, 2020, Boston Scientific issued a recall of the ICD "due to a manufacturing defect wherein a potential short-circuit that could cause significant complications, including, but not limited to, patients experiencing less shock than intended or no shock at all." ECF 14 at ¶ 9. Welz further alleges that in a December 2020 Medical Device Advisory, Boston Scientific stated that "variations in header assembly allowed a very small pathway for moisture ingress enabling a shorting condition to occur during delivery of high voltage therapy" and that "a header assembly subprocess was

found to be subject to process variations directly contributing to this behavior." ECF 14 at ¶ 10.[3]

The MDA and Federal Preemption

The MDA expressly preempts certain state laws. Subject to some unrelated exceptions, "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."

21 U.S.C. § 360k(a). The United States Supreme Court has articulated a two-part test for applying the express preemption principles codified in Section 360k of the MDA. *See Riegel*, 552 U.S. at 321–22. The test requires the court to examine the particular federal laws and regulations applicable to the device in question and compare them to the state claims the plaintiff wishes to bring. First, a court must determine whether "the Federal Government has established requirements" applicable to a particular device. Second, the court must determine whether a plaintiff's claims "are based upon [state] requirements with respect to the device

[3] Because these allegations appear in the Amended Complaint, I need not, and therefore do not, consider the documents attached to plaintiff's opposition to the motion to dismiss.

that are different from, or in addition to the federal ones, and that relate to safety and effectiveness." *Id.* If the Court answers both questions in the affirmative, the state laws are expressly preempted by the MDA. *Id.* at 321-23. However, "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* at 330.

Premarket approval is a federal "requirement" that meets the first prong of the test for Section 360k preemption. *Riegel*, 552 U.S. at 322–23 (PMA was "specific to individual devices" and "focused on safety, not equivalence."). As for the second prong of the Section 360k preemption test, included in the meaning of "state requirements" subject to federal preemption are common law causes of action, such as negligence and strict liability. *Id.* at 323-244.

In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Supreme Court construed § 337(a) of the MDA—which provides that all actions to enforce FDA requirements "shall be by and in the name of the United States"—"as barring suits by private litigants 'for noncompliance with the medical device provisions.'" *In re Medtronic*, 623 F.3d at 1204 (quoting *Buckman*, 531 U.S. at 349 n. 4). The Eighth Circuit Court of Appeals has read *Buckman* and *Riegel* together to create only a "narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption." *Id.* (quoting *Riley v.*

Cordis Corp., 625 F. Supp. 2d 769, 777 (D. Minn. 2009)). As such, a plaintiff "must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *In re Medtronic*, 623 F.3d at 1204 (quoting *Riley*, 625 F. Supp. 2d at 777) (italics in original).

Here, Boston Scientific argues that Welz's claims are expressly preempted by the MDA. The parties do not dispute that the first prong of the *Riegel* test is satisfied, as the ICD was subjected to PMA and is thus governed by the specific requirements set forth in the PMA Supplement.

Boston Scientific argues that "plaintiff's Amended Complaint is devoid of any allegations to substantiate a viable design defect and/or failure to warn claim. Nowhere in the amended pleading does Plaintiff attempt to plead violations of federal requirements related to the FDA-approved design or warnings associated with the device at issue." ECF 16 at 16. Boston Scientific attempts to characterize the Amended Complaint as pleading only design defects, and in doing so ignores the fact that plaintiff alleges *manufacturing* defects, which survive preemption. In opposition to dismissal, plaintiff argues that he only pleads claims for manufacturing defects, and in doing so ignores the fact that the Amended

Complaint also alleges (albeit in conclusory fashion) *design* defects, as well as claims for failure to warn. *See* ECF 14 at ¶¶ 11-28 and 43-44.

State law claims based on allegations of a manufacturer's failure to comply with device-specific PMA specifications survive preemption. *See Sullivan*, 498 F. Supp. 3d at 1114-15*; Edwards, Trustee for Herrman v. Thoratec LLC*, 532 F. Supp. 3d 786, 792 (D. Minn. 2021); *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 898-99 (M .D. Pa. 2017) (claim that device was manufactured out of specification not preempted); *In re Medtronic Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1161 n.17 (D. Minn. 2009) ("[A]n adequately pleaded claim that a specific device was not manufactured in accordance with its PMA specifications can survive preemption."); *Warren v. Howmedica Osteonics Corp*., Case No. 4:10CV1346 DDN, 2011 WL 1226975, at *5 (E.D. Mo. Mar. 29, 2011) ("[B]ecause plaintiffs allege that defendants violated a federal requirement specific to the FDA's PMA approval of [the device], plaintiffs' claims survive preemption.") (internal quotation marks and citation omitted).

Welz clearly pleads manufacturing defects, and in opposition to dismissal insists that he *only* pleads manufacturing defects as a basis for his strict liability and negligence claims. To the extent his conclusory references to design defects, as recited above, amount to an attempt to plead claims for strict liability and negligence based on design defects, those claims are preempted and dismissed.

See In re Medtronic, 623 F.3d at 1206 (design defect claims are "attacks on the risk/benefit analysis that led the FDA to approve an inherently dangerous Class III device. Such claims are expressly preempted.") (cleaned up). However, the claims stated in Counts I and III of the Amended Complaint are not preempted to the extent they allege that Boston Scientific's failures to manufacture the ICD in accordance with the PMA and PMA Supplement violate Missouri law.

Although Boston Scientific complains that Welz's Amended Complaint is not specific enough as to how his ICD was not manufactured in compliance with the PMA, the Eighth Circuit has recognized "the care that courts must exercise in applying *Riegel*'s parallel claim principle at the pleading stage, particularly to manufacturing defect claims." *In re Medtronic*, 623 F.3d at 1207. The Court must be mindful not to hold Welz "to an impossible pleading standard." *Id.* at 1206. Here, Welz has done more than simply allege that Boston Scientific has violated unspecified or generic federal regulations; he has set out how the ICD was manufactured outside the specifications of the PMA and alleged the ways that those defects caused his device to fail and injure him. As such, he is entitled to conduct discovery to support his claims. I thus conclude that Counts I and III of Welz's Amended Complaint sufficiently allege a specific federal violation for claims rooted in manufacturing defects.

However, the same cannot be said of the failure to warn claims alleged in Counts II and IV of the Amended Complaint. Welz omits any reference to, or discussion of, these claims in opposition to dismissal, prompting Boston Scientific to argue in its reply brief that Welz has abandoned these claims and/or concedes that they should be dismissed. Given Welz's failure to address these claims in opposition to dismissal and his repeated insistence that he only brings claims for manufacturing defects, in the absence of any allegations that Boston Scientific modified or failed to include FDA-approved warnings about the ICD the Court concludes that Welz's failure to warn claims alleged in Counts II and IV of the Amended Complaint are preempted. *In re Medtronic, 623 F.3d at 1205* (failure to warn claims alleging that state law requires a device manufacturer to give additional warnings about Class III devices are "different from or in addition to" federal requirements and therefore preempted); *see also Williams v. Bayer Corp.*, 541 S.W.3d 594, 609 (Mo. Ct. App. 2017) (under Missouri law, claim based on failure to warn of problems with Class III implanted device was expressly preempted under MDA). Counts II and IV are accordingly dismissed.

The next issue is whether Welz's state law claims for manufacturing defects are "different from, or in addition to" federal requirements and, if not, whether

such claims would give rise to liability under state law even if the FDCA had never been enacted.[4] *Riegel*, 552 U.S. at 321-23; *Buckman*, 531 U.S. at 353.

Count I of Welz's Amended Complaint alleges a claim of strict liability for manufacturing defects under Missouri law. To make a submissible case, Welz has to prove:

> (1) the defendant sold a product in the course of its business; (2) the product was then in a defective condition, unreasonably dangerous when put to a reasonably anticipated use; (3) the product was used in a manner reasonably anticipated; and (4) the plaintiff was damaged as a direct result of such defective condition as existed when the product was sold.

Coterel v. Dorel Juvenile Group, Inc., 827 F.3d 804, 808 (8th Cir. 2016) (quoting *Columbia Mut. Ins. Co. v. Epstein*, 239 S.W.3d 667, 671 (Mo. Ct. App. 2007)). In Missouri, a manufacturing defect occurs when something goes wrong in the manufacturing process and the product deviates from its intended condition. *Gillan v. Wright Med. Tech. Inc.*, 396 F. Supp. 3d 844, 848 (E.D. Mo. 2019) (citing *Smith v. Brown & Williamson Tobacco Corp.*, 275 S.W.3d 748, 791 (Mo. Ct. App. 2008)).

In support of this claim, Welz alleges that: the ICD implanted into him was manufactured in deviation of the manufacturing specifications set out in the PMA; these manufacturing defects rendered the ICD defective and unreasonably

[4] There is no dispute that the claims brought by Welz "relate to the safety or effectiveness" of the device.

dangerous when put to its reasonably anticipated use; the ICD was defective because it allowed moisture ingress into the device enabling a shorting condition to occur, causing the device to fail to deliver shocks, deliver less shock than intended, fail to respond to a device check-in, and fail to issue appropriate battery alerts; and that as direct result of the ICD's manufacturing defects, he was injured.

In support of his claim of negligent manufacturing defects[5] in Count III of his Amended Complaint, Welz alleges: the ICD implanted in him was manufactured in violation of the PMA specifications as described in Count I; Boston Scientific owed him a duty under Missouri law to use reasonable care to manufacture the ICD to be reasonably safe; Boston Scientific was negligent in failing to use reasonable care in manufacturing the ICD and manufactured the device in a way that did not comply with the PMA requirements; and as a direct result of Boston Scientific's negligence, he was injured.

These claims as pleaded by Welz in Counts I and III of the Amended Complaint do not attempt to impose responsibilities on Boston Scientific that are

[5] Under Missouri law, "in an action for negligence, generally, a plaintiff must allege ultimate facts which if proven, show: (1) the existence of a duty on the part of the defendant to protect the plaintiff from injury; (2) failure of the defendant to perform that duty; and (3) injury to the plaintiff resulting from such failure." *Redd v. DePuy Orthopaedics, Inc.*, 48 F. Supp. 3d 1261, 1270 (E.D. Mo. 2014). "Thus, in order to recover on a claim for negligent manufacture, a plaintiff must establish that the defendant failed to use ordinary case to manufacture the product to be reasonably safe." *Id.* (cleaned up).

different from, or in addition to, the federal requirements, and sufficiently plead violations of parallel Missouri law such that they are not preempted.

Accordingly,

IT IS HEREBY ORDERED that defendant's motion to dismiss [15] is granted as to Counts II and IV of the Amended Complaint, and to Counts I and III only to the extent that Counts I and III plead design defects as a basis for the strict liability and negligence claims; in all other respects, the motion to dismiss is denied as to Counts I and III.

This case will be set for a Rule 16 scheduling conference by separate Order.

CATHERINE D. PERRY
UNITED STATES DISTRICT JUDGE

Dated this 20th day of September, 2024.